

Testing of Junctional Tourniquets by Military Medics to Control Simulated Groin Hemorrhage

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ABSTRACT

Background: Junctional hemorrhage is a common cause of death on the battlefield, but there is no documented direct comparison for the use of junctional tourniquet models by US medics. The purpose of this testing is to assess military medic experience with the use of junctional tourniquets in simulated out-of-hospital trauma care. **Methods:** Nine medics (seven men and two women) used four different junctional tourniquets: Combat Ready Clamp™ (CRoC™; <http://www.combatmedicalsystems.com>), Abdominal Aortic and Junctional Tourniquet™ (AAJT™; <http://www.compressionworks.net>), Junctional Emergency Treatment Tool (JETT™; <http://www.narescue.com>), and SAM Junctional Tourniquet® (SJT®; <http://www.sammedical.com/products>). These medics also acted as simulated casualties. Effectiveness percentages, as measured by stopped distal pulse by Doppler auscultation, and time to effectiveness were recorded in two tests per tourniquet (72 total tests). Tourniquet users ranked their preference of model by answering the question: “If you had to go to war today and you could only choose one, which tourniquet would you choose to bring?” **Results:** All tourniquets used were safe under the conditions of this study. Both the SJT and the CRoC had high effectiveness percentages; their rate difference was not statistically significant. The SJT and the CRoC had fast times to effectiveness; their time difference was not statistically significant. Users preferred the SJT and the CRoC; their ranked difference was not statistically significant. **Conclusion:** The SJT and the CRoC were equally effective and fast and were preferred by the participants.

KEYWORDS: *tourniquets, hemorrhage, resuscitation, groin, inguinal, medical device, injuries and wounds*

Introduction

Since publication of the book *Black Hawk Down*, which describes the US military experience in Mogadishu, Somalia, in 1993, the US military has become increasingly aware of the clinical problem of controlling hemorrhage

from junctional wounds—those at the junction of the trunk and its appendages.^{1,2} Not only has the rate of junctional hemorrhage risen, but also junctional hemorrhage itself is often lethal even with adjuncts that include the use of QuikClot® Combat Gauze™ (<http://www.z-medica.com/healthcare/Products>).^{3–5} Junctional bleeding is a common preventable cause of death on the battlefield.^{4,6} In a survey of US military war casualty data, junctional wounds amenable to junctional tourniquets increased 14-fold over a decade among 833 casualties; 145 of the 833 died of wounds, but none had a junctional tourniquet placed.⁵

Tai and Dickson of Great Britain’s military medical services introduced the term “junctional zone trauma” in 2009 when describing a gap in the care of challenging wounds.⁷ Efforts to address this capability gap in hemorrhage control on the battlefield have led to the development of junctional tourniquets, four of which are currently approved for use in the United States by the US Food and Drug Administration.^{5,8} Feasible procedures for removing such deficiencies have been outlined.^{9–15} However, evidence did not exist that would distinguish the tourniquets. To provide such evidence, the current study used medics in a simulated out-of-hospital situation to compare multiple junctional tourniquets.

Methods

A US Army Institute of Surgical Research (USAISR) protocol was approved by the dean of the US Army Medical Department Center & School under the guidance of the US Army Human Research Protection Office (Customer Assessment by US Military Medics for User Preference Testing of Junctional Tourniquets in Simulated Out-of-Hospital Care). This test plan deliberately involved operators who were similar to the end-users: North Atlantic Treaty Organization (NATO) medics. The two test assessors were an experienced clinician-scientist with expertise in tourniquets and a master instructor for the US Army combat medics. All testers (medics) were from the Army and were mid-grade enlisted noncommissioned

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officers (NCOs) of the rank of staff sergeant (E-6; Military Occupational Specialty 68W, Healthcare Specialist); 100% had combat experience.

Before working with human subjects, these medics were trained to proficiency by the assessors through the use of (1) online videos, (2) user hardcopy instructions, (3) device handling, and (4) three consecutive, successful uses of the device on a manikin (CRoC Trainer Manikin, Operative Experience, Inc.; <http://operativeexperience.com/>). Ten medics were trained to proficiency. One medic withdrew from the testing because of a recurrence of mild, temporary, and focal abdominal discomfort associated with polycystic ovarian disease. The discomfort recurred in the first seconds of use of the first device applied, so testing was not completed for this individual. The nine remaining medics participating in the present study (seven men and two women) tested the tourniquets on one another; the participants alternated between being testers and simulated casualties.

At the time of the study, the US Food and Drug Administration (FDA) had approved only four models of junctional tourniquet for inguinal hemorrhage control (Table 1) in the United States. These tourniquets were the CRoC, AAJT, JETT, and SJT. Because the inguinal area was the only indicated body area that all four tourniquets shared, it was used as the testing site. The right groin was assessed first; the left groin was assessed second. Unilateral groin hemorrhage was simulated.

Each tester used each of the four models of tourniquet two times (once on the left and once on the right side of

the groin), so the number of tests for a tester was eight (four models \times two sides); a tester applied the four tourniquets for a total of eight times to one casualty. This testing resulted in a total of 72 tests (nine testers \times four devices \times two sides).

The focus of the testing was the medics' experience in tourniquet use. The surrogate for bleeding was the presence of a distal pulse detected by using hand-held Doppler transducer (Nicolet Vascular Elite Model 100; Viasys Healthcare, Conshohocken, PA), which makes an audible pulse sound. Pulse absence represented hemorrhage control. Effectiveness was defined as stopping the distal pulse by Doppler auscultation. The distal pulse check was in the leg (Doppler flow detection) in the posterior tibialis artery at the ankle.

Safety was defined as an absence of adverse events (any undesirable sign, symptom, or medical or psychological condition). Uncomplicated pain that resolved promptly after device use was not considered an adverse event even if the subject stopped the test iteration due to pain. Safety issues were sought by observation during the testing by the two assessors in real-time. The subjects were assessed throughout the duration of testing, which took 3 hours of the subject's time.

Tourniquets were placed near the user open and ready for use; the tourniquets were neither packaged nor packed away. In testing, the tourniquets were put on or near the groin in accordance with the instructions for use of each model. The AAJT was applied to the umbilicus; other models were applied to the groin. The order of testing

Table 1 *Junctional Tourniquet Traits for Models That Are Currently US FDA Cleared*

Name of Tourniquet Model	Combat Ready Clamp	Abdominal Aortic and Junctional Tourniquet	Junctional Emergency Treatment Tool	SAM Junctional Tourniquet
Short name	CRoC	AAJT	JETT	SJT
Maker	Combat Medical Systems	Compression Works	North American Rescue Products	SAM Medical Products
City, state	Fayetteville, NC	Hoover, AL	Greer, SC	Wilsonville, OR
510(k) date(s)	8/11/10; 4/29/13	10/18/11; 12/6/2013	1/3/13	3/18/13, 7/24/13
FDA number(s)	K102025; K130482	K112384, K133029	K123194	K123694; K131561
NSN	6515-01-589-9135	6515-01-616-4999	6515-01-616-5841	6515-01-618-7475
Cost (\$USD, est. USG)	654	515	220	292.50
Weight (g)	799	485	651	499
Cube (L)	0.8	1.4	1.6	1.5
Indication(s)	Battlefield, difficult inguinal or axilla bleeds	Battlefield, difficult inguinal, pelvis, or axilla bleeds	Difficult inguinal bleeds	Difficult inguinal or axilla bleeds, or pelvic fracture immobilization

Source: FDA, US Food and Drug Administration; NSN, National Stock Number; USD, US dollars; USG, US government; 510(k) is the FDA clearance.

was CRoC, AAJT, JETT, and SJT, based, as noted earlier, on their date of FDA clearance for the inguinal indication. The combat uniform was worn, although boots and socks were removed during testing. Testers had a 5-minute rest period between test iterations. Hence, all tests were conducted on a given subject within a 3-hour time period. The test location was a work room of the Department of Combat Medic Training at the US Army Medical Department Center & School.

Test results included effectiveness percentages, time of application, and ranked preferences. After testing, users ranked tourniquet performance subjectively.^{16,17} Users ranked their preference of the tourniquets by answering the question, "If you had to go to war today and you could only choose one, which tourniquet would you choose to bring?" The rank, R, was a whole number ascribed by a user to a given device (rank = 1, "best"; 4, "worst"). The rank was converted into a score (score = 5 minus rank). The users' scores by model were summed. For nine users with 4 points allotted to the best rank, the best possible score was 36 and the worst possible score was 9.

Statistical testing included repeated measures analysis of variance (ANOVA) to see if any device was different from the others (SAS Institute, Cary, NC). Pairwise comparisons were adjusted using Tukey's method. Comparison of proportions such as effectiveness percentages was made with χ^2 test using SAS (SAS Institute, Cary, NC) and MS Excel 2003 (Microsoft, Redmond, WA). Descriptive statistics were used to portray results. Significance for results was established when p values were < .05.

Results

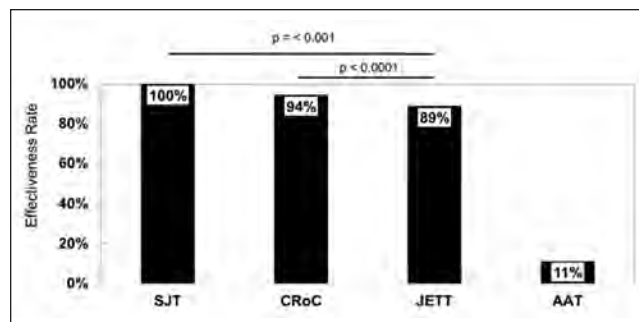
Safety Results

Based on the definition of safety used in the present study, all tourniquet uses were safe in the absence of adverse events during the 3 hours of testing. The four models of tourniquets were equally safe.

Effectiveness Results

The effectiveness percentages varied by model of junctional tourniquet ($p < .003$). Effectiveness percentages by junctional tourniquet model were statistically stratified into two groups with a pair of models of tourniquet in each group. The most effective junctional tourniquets were the SJT (100%) and the CRoC (94%), which did not differ significantly from each other ($p = .187$; Figure 1). However, the CRoC was more effective than both the JETT and AAJT ($p < .001$), and the SJT was also more effective than both the JETT and AAJT ($p < .001$). Differences in the effectiveness of the JETT and the AAJT were not statistically different ($p = .991$). The effectiveness rate of the AAJT was 11%; this low effectiveness

Figure 1 Effectiveness percentages by model of junctional tourniquet. The SJT and the CRoC had the highest effectiveness percentages; their difference was not statistically significant. The JETT and the AAJT had significantly lower effectiveness percentages than the SJT and CRoC.



rate was attributed to the fact that the AAJT hurt so often and to such a degree that the simulated casualties commonly stopped the iteration of use early before effectiveness was attained.

Of the nine users, only two were able to make effective use of each of the four models of junctional tourniquet in one or more tests; however, 16 of the total 19 ineffective tests were made with use of the AAJT. For all 72 tests, the average effectiveness rate was 74% (53 of 72).

The effectiveness rate for the left side was 69% (25 of 36), and the effectiveness rate for the right side was 79% (28 of 36). Although the order of testing was always left first and right second, so that the users had fresh experience before they used the junctional tourniquet models on the right side, the difference in effectiveness rate by side (left versus right) was not statistically significant ($p = .643$).

Time to Effectiveness Results

Because the AAJT hurt to such a degree that the simulated casualties stopped early the iteration of use, the AAJT was removed from further statistical analysis of time to effectiveness. For the three remaining models, the times to effectiveness varied by junctional tourniquet model ($p < .003$; Figure 2). Both the CRoC and SJT models (which did not differ [$p = .090$]) were more rapidly effective than the JETT ($p \leq .008$). Average time to effectiveness by side (left versus right) did not differ ($p = .094$). However, the left side, being first in order of testing, took longer (average ~150 seconds) than the right side (average ~90 seconds; data not shown).

Subjectively Ranked Performance Results

Preferences of users for junctional tourniquets were different ($p < .001$). Users most often preferred the CRoC and SJT over other models ($p < \text{ANOVA probability}$) but had no preference between these two models ($p = .187$; Figure 3, Table 2).

Figure 2 Time to effectiveness by model of junctional tourniquet. Average time to effectiveness in seconds varied by model of junctional tourniquet. The SJT and CRoC had the fastest times to effectiveness; their difference was not statistically significant. The AAJT had too few effective tests to analyze meaningfully. The JETT had the slowest times to effectiveness. Each column represents the mean and each bar notes the standard deviation of the sample.

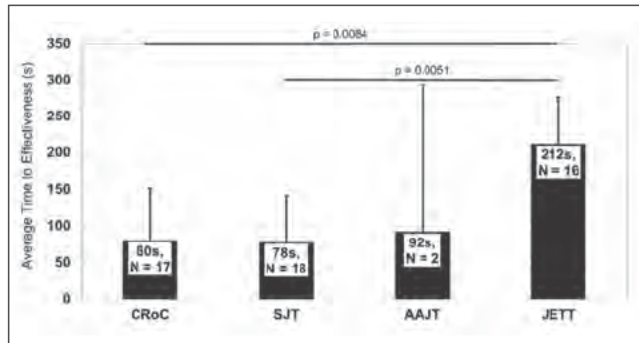
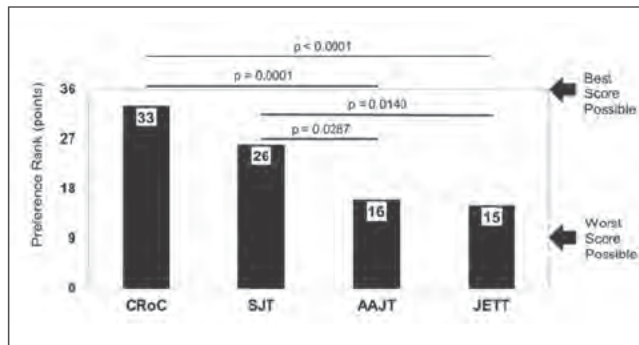


Figure 3 Medic ranking of preference for junctional tourniquet models. Preferences for CRoC versus SJT and AAJT versus JETT did not differ ($p > .05$).



Discussion

The first major finding of the present junctional tourniquet testing was that medics preferred the CRoC and SJT and ranked them highest. Conversely, these medic users ranked the AAJT and the JETT as the worst.

The second major finding was that the effectiveness rate for the four models tested varied from 11% to 100%. The most effective junctional tourniquets tested were the SJT and CRoC. The next most effective model was the JETT. A low effectiveness rate was associated with severe pain with the AAJT to such a degree that the simulated casualties stopped the test iteration in the remaining 89% of uses—all of which were therefore ineffective. Because the SJT and CRoC were ranked best and were most effective, the first and second main findings were concordant.

A minor finding of the testing was that no safety issues arose because no adverse events occurred; the four devices were equally safe. Longer-term studies would be needed to verify the safety of these models. Informally, medics said that comfort varied by model; they reported the most comfortable junctional tourniquet was the CRoC. The most uncomfortable junctional tourniquet was the AAJT. Pain felt may have affected preference; the lowest ranked tourniquet exerted the most pain, and the highest ranked tourniquet exerted the least pain. Additionally, while the CRoC had 94% effectiveness versus 100% for the SJT, medics ranked the CRoC over the SJT by a difference that was not statistically significant; the preference may be affected by the superior CRoC comfort, which may be a crossover effect from simulated casualty experience into user rankings. In a previous study, the CRoC was also found to have the least pain of the four junctional tourniquets; however, because testers were also subjects, the experience as subjects may have influenced their experience as testers (J.F. Kragh Jr, unpublished observations).

The strength of the present testing is that it offers a direct comparison by military medics of the four currently FDA-approved junctional tourniquets. This strength fills a specific knowledge gap for junctional tourniquets on their differential performance in the hands of medics. Such new knowledge may aid decision-makers in

Table 2 Ranked Preferences of Junctional Tourniquet by Model

Rank*	Score	User Preference by Model				Score by Model			
		CRoC	AAJT	JETT	SJT	CRoC	AAJT	JETT	SJT
1	4†	7‡	0	0	2	28§	0	0	8
2	3	1	2	1	5	3	6	3	15
3	2	1	3	4	1	2	6	8	2
4	1	0	4	4	1	0	4	4	1
Sum		9	9	9	9	33	16	15	26

Notes: *Rank 1 = best; Rank 4 = worst.

†Points assigned to the highest rank of 1.

‡Number of users who gave this tourniquet a rank of 1 = best.

§Score for each tourniquet (No. of users × score).

choosing which one to provide medics in the future. The present testing closely followed a similar study conducted by military physicians (J.F. Kragh Jr, unpublished observations). In normal human volunteers and using similar methods as to those in the present testing, the prior study was consistent with the current testing as it also found that the CRoC and SJT performed well among the four models.

Limitations of the present testing are numerous. The absence of the Navy and Air Force testers limits the generalizability of the results. The test plan was constrained by a common FDA-approved indication for inguinal bleeding; therefore, that was the region of use. The axilla and other areas were unassessed; the AAJT was not cleared at the time of the testing for groin use except by central application through periumbilical aortic compression.

After the present testing occurred, the AAJT received a newly FDA-approved indication for unilateral groin application. This new indication means that the AAJT can now be placed directly on the inguinal area to control ipsilateral inguinal hemorrhage instead of being placed on the periumbilical area for a unilateral inguinal hemorrhage. The two compression sites, periumbilical and groin, for the inguinal indication in question for the AAJT, appear to have substantially different pain levels as the groin placement is more comfortable (M. Lyon, et al., unpublished observations). Because the present test preceded clearance of direct inguinal application, the test plan subsequently became biased against the AAJT. The time allotted to training before testing was limited; more training time may have been beneficial for the JETT and AAJT.

The findings of this study offer many directions for further testing. The differential performance of junctional tourniquets by other assessors such as US Navy corpsmen, US Air Force medics, and medics of US allies in field testing of tourniquets may yield knowledge for decision makers. Combat lifesavers, junior-grade medics, or Special Operations paramedics may be alternative surrogates of the intended battlefield user rather than the medics who were the users in the present test; the present medics were instructors of new medics.

Currently, there is insufficient knowledge to determine whether ranking within an arbitrary point spread threshold, such as a difference of 10 points, could delineate clinical impact from no impact. Axillary testing would be useful and reassessment of the AAJT is needed because its labeling has changed. Although neither was statistically significant, the differences between right and left side use may indicate user learning as the right side performance had 9 percentage points more

in effectiveness rate and 57 seconds less in average time to effectiveness; future assessments may include learning metrics.

In summary, new evidence of junctional tourniquets used by medics for difficult inguinal bleeding indicates that the SJT and the CRoC performed well and were preferred by the testers.

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Disclaimers

The opinions or assertions contained herein are the private views of the authors and are not to be construed as official or reflecting the views of the Department of Defense or United States Government. The authors are employees of the US Government. This work was prepared as part of their official duties and, as such, there is no copyright to be transferred.

Disclosures

The authors declare no conflicts of interest.

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